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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,332	01/09/2001	Samuel I. Achilefu	MRD-66	5505

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1616	14

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/757,332	Applicant(s) ACHILEFU ET AL.	
	Examiner D. L. Jones	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/18/03; 8/25/03; and 10/9/03* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-3,13-15 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-12,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2 & 13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 12, filed 8/25/03, wherein the specification was amended.

Note: Claims 1-20 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to compound and uses thereof as wherein the compound is that encompassed in the formula set forth in independent claim 1.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election with traverse of Group II (claims 4-12, 16, and 17) in Paper No. 11, filed 7/18/03, is acknowledged. The traversal is on the ground(s) that the restriction is improper because all the claims are directed to compounds encompassed in the formula of independent claim 1. Specifically, Applicant asserts that the claims have unity of invention since the compound share a benzoindole structure and have the same utile as cyanine dye bioconjugates including bioactive molecules for diagnosis and therapeutic purposes. This is found non-persuasive because the inventions are distinct and each requires a separate search of the prior art. It should be noted that the claims could have been restricted according to the various definitions of the variables W3 and X3, or B1, C1, or D1 because depending upon the value assigned to the variables the various groups of compounds classify differently. However, in an attempt to choose a restriction method that would allow a greater portion of the invention to be

search, if applicable, a restriction between the compounds, method of diagnostic use, and method of therapeutic use was done. As set forth, the groups of compounds are actually distinct from one another depending on the variable definitions. Likewise, the methods are distinct from one another because the use of a compound in a diagnostic method does not mean that it can be used for therapeutic purposes as well. A diagnostic method enables one to determine whether is present or not. A therapeutic method involves the use of some type of therapy (e.g., treatment) using the compound of interest. Also, it should be noted that a separate search is necessary for the diagnostic and therapeutic methods and for the various groups of compounds generated by the variable assignments. Hence, the restriction requirement is still deemed proper and is therefore made FINAL.

Notes: (1) Claims 4-12, 16, and 17 were examined *only* to the extent that they read on a method of performing a diagnostic procedure as set forth in independent claim 4. Initially, Applicant's elected species was searched. However, since no prior art could be found to reject Applicant's method claims, the search was extended over the full scope of Group II. Applicant's elected group, Group II is allowable over the prior art of record because the prior art neither anticipates nor renders obvious a diagnostic method wherein a compound as set forth in independent claim 4 is administered to a subject. It should be noted that while the claims are allowable over the prior art of record, Applicant MUST address and overcome the double patenting and 112 rejections set forth below.

WITHDRAWN CLAIMS

4. Claims 1-3, 13-15, and 18-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

STATUTORY DOUBLE PATENTING

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 4-12, 16, and 17 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 4-12, 16, and 17 of copending Application No. 09/757,333. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

OBVIOUSNESS-TYPE DOUBLE PATENTING

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 4-12, 16, and 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 9, 15-17, and 19 of copending Application No. 09/981,206. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a diagnostic method wherein a subject is administered a compound that is encompassed by the formula of independent claim 4. The claims differ in that the

claims of 09/981,206 encompass other components that are not included in the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 REJECTIONS (First Paragraph)

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not provide enablement for preventing in vivo or in vitro fluorescence quenching. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The disclosure of the instant invention is directed to compounds and methods of performing a diagnostic and therapeutic procedures by using compounds encompassed in independent claim 1. Since, the claims have been found to be allowable over the prior art of record as set forth above, a skilled practitioner in the art would not know that in vivo or in vitro fluorescence quenching is possible absent evidence or knowledge in the art that when such compounds are used in the methods quenching does not occur. Thus, prevention of quenching indicates that the compounds used in the methods *never* allow situations wherein quenching does not occur to take place. Hence, the amount of guidance present in the specification, the absence of data indicating that the conditions always result in the prevention of quenching when the compounds are used, and the state of the prior art indicating that diagnosis using the compound is possible, all indicate that inhibition, not prevention is possible. Also, the amount of guidance necessary to perform Applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous compounds to determine which ones prevents quenching. Hence, the amount of guidance present in the specification fails to present the necessary instruction such that one can readily determine the if the compound prevent quenching in all instances (in vivo and in vitro).

Note: The Examiner respectfully suggests that Applicant replace the term 'prevent' with 'inhibit' or 'reduce'.

COMMENTS/NOTES

11. The Examiner is aware of numerous documents submitted by Applicant containing matter encompassed by the instant invention. Thus, Applicant is respectfully requested to submit a listing of all applications containing overlapping subject matter.

While the Examiner has conducted an inventor's search to obtain such documents, Applicant's listing would serve to cover any applications inadvertently missed by the Examiner.

12. Applicant is respectfully requested to review the supplemental information disclosure statement filed on 10/9/03, Paper No. 13. It appears that the disclosure state was submitted in the wrong application.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

October 27, 2003